

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

_____	)	
PENNSYLVANIA EMPLOYEE BENEFIT	)	
TRUST FUND, on behalf of itself and all	)	
others similarly situated, JOSEPH	)	
MACKEN, and COMMISSIONER LINDA	)	
A. WATTERS	)	
	)	
Plaintiffs,	)	
	)	Civ. No. 05-075-SLR
v.	)	(Lead Case)
	)	
ZENECA, INC. and ASTRAZENECA	)	
PHARMACEUTICALS, LP,	)	
	)	
Defendants.	)	
_____		

**DEFENDANTS' REQUEST FOR JUDICIAL NOTICE  
IN SUPPORT OF THEIR MOTION TO DISMISS**

Defendants AstraZeneca Pharmaceuticals, L.P. and Zeneca Inc., (collectively "AstraZeneca") respectfully submit this Request for Judicial Notice in Support of their concurrently filed Motion to Dismiss ("Motion").

In ruling on a motion to dismiss, a court may consider documents "integral to or explicitly relied upon in the complaint." *See, e.g., Angstadt v. Midd-West Sch. Dist.*, 377 F.3d 338, 342 (3d Cir. 2004) ("we have recognized that '[a]lthough a district court may not consider matters extraneous to the pleadings, a document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment"); *Lum v. Bank of Am.*, 361 F.3d 217, 221-22 n.3 (3d Cir. 2004) ("In deciding motions to dismiss pursuant to Rule 12(b)(6), courts generally consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form

the basis of a claim. A document forms the basis of a claim if the document is ‘integral to or explicitly relied upon in the complaint.’”) (citation omitted); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (“an exception to the general rule is that a ‘document *integral to or explicitly relied upon in the complaint*’ may be considered ‘without converting the motion [to dismiss] into one for summary judgment’”) (citation omitted; emphasis in original).

In ruling on a motion to dismiss, a court may also consider matters of which it can take judicial notice. *See, e.g., In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002) (affirming district court’s consideration of judicially noticed documents in granting motion to dismiss); *Township of South Fayette v. Allegheny County Housing Auth.*, 27 F. Supp. 2d 582, 594 (W.D. Pa. 1998) (“It is well established that courts are permitted to consider matters of which they may take judicial notice, including records and reports of administrative bodies”); *Diceon Elecs., Inc. v. Calvary Partners, L.P.*, 772 F. Supp. 859, 861 (D. Del. 1991) (“On a motion to dismiss the Court is free to take judicial notice of certain facts that are of public record if they are provided to the Court by the party seeking to have them considered. Securities and Exchange Commission (‘SEC’) filings fall within this category of public records that can be judicially noticed.”).

Specifically, in ruling on a motion to dismiss, a court may take judicial notice of, and consider, documents available on the official website of the Food and Drug Administration (“FDA”). *See In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (“the Court will take judicial notice of the FDA’s Center for Drug Evaluation and Research Listing of New & Generic Drug Approvals 1998-2003 and its listing of bupropion hydrochloride which is available at <http://www.fda.gov/cder/approval/b.htm>”); *see also In re Vertex Pharm., Inc. Sec. Litig.*, 357 F. Supp. 2d 343, 352 n.4 (D. Mass. 2005) (taking judicial

notice of “FDA policy” appearing on FDA’s official website in ruling on motion to dismiss); *see also Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 940-43 (7th Cir. 2001).

Here, Plaintiffs expressly rely upon, and quote, the FDA-approved labeling (or “package insert”) for NEXIUM® (esomeprazole magnesium) in their Consolidated Class Action Complaint (“Complaint”) (D.I. 20). Compl. ¶ 75. Indeed, in the class action complaints that Plaintiffs Watters and Macken filed before they agreed to consolidate their cases, they reproduced the charts contained in the Nexium labeling that summarize the results of the studies that AstraZeneca used to obtain FDA approval for Nexium. *See Watters Class Action Complaint* (D.I. 1), ¶¶ 80, 82; *Macken Class Action Complaint* (D.I. 1), ¶¶ 41, 43.

Moreover, as explained in more detail on pages 5-8 of AstraZeneca’s concurrently filed Opening Brief in Support of its Motion to Dismiss: (1) the labeling for prescription and over-the-counter drugs, including Nexium, PRILOSEC® (omeprazole), and Prilosec OTC™ (omeprazole magnesium), must be approved by the FDA in connection with a New Drug Application (“NDA”); (2) the FDA approved AstraZeneca’s NDAs for Nexium, Prilosec, and Prilosec OTC; (3) the FDA approved the labeling for Nexium, Prilosec, and Prilosec OTC; (4) the results of clinical studies that were submitted to the FDA as part of the Nexium NDA are reflected in the Nexium labeling; (5) the labeling contains the approved indications for the drug, as well as the FDA-approved doses for the drug; and (6) once the FDA has approved a new drug, the manufacturer has the right to market the drug in accordance with the FDA-approved labeling. Thus, because Plaintiffs’ Complaint challenges every aspect of the marketing of Nexium, from its development to its FDA approval to its pricing and promotion, the labeling for Nexium, Prilosec, and Prilosec OTC is integral to the claims in Plaintiffs’ Complaint.

In addition, the FDA-approved Nexium, Prilosec, and Prilosec OTC labeling attached hereto are available on, and were downloaded from, the FDA's official website, [www.fda.com](http://www.fda.com). See Ex. 1, Nexium Labeling, *available at* [http://www.fda.gov/cder/foi/nda/2001/21154\\_Nexium\\_prntlbl.pdf](http://www.fda.gov/cder/foi/nda/2001/21154_Nexium_prntlbl.pdf) (last visited June 30, 2005); Ex. 2, Prilosec Labeling, *available at* <http://www.fda.gov/cder/foi/label/2002/19810s074lbl.pdf> (last visited June 30, 2005); Ex. 3, Prilosec OTC Labeling, *available at* [http://www.fda.gov/cder/foi/nda/2003/21-229\\_Prilosec\\_prntlbl.pdf](http://www.fda.gov/cder/foi/nda/2003/21-229_Prilosec_prntlbl.pdf) (last visited June 30, 2005).

For the foregoing reasons, AstraZeneca respectfully requests that the Court consider, and take judicial notice of, the Nexium, Prilosec, and Prilosec OTC labeling in ruling on the Motion.

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